REMARKS

I. Status of the Application.

The original application, United States Patent Application No. 10/730,495, was filed December 5, 2003, with a Request for Continued Examination (the "RCE") filed September 26, 2005 (the "present application"). Concurrent with the filing of the RCE, claims 1-2 and 5-17 were cancelled, and new claims 18-27 were added. Therefore, claims 3, 4 and 18-27 were previously pending in the present application.

In a non-final Office Action dated March 21, 2006 (the "Office Action"), Examiner Celia Chang: (1) noted that claims 18-24 and 27 were provisionally elected by Applicants' prior counsel on March 14, 2006, and requested confirmation of the election; (2) rejected claims 18-24 as failing to comply with the written description and enablement requirements under 35 U.S.C. § 112, (3) rejected claims 18-24, and 27 under 35 U.S.C. 103(a) as being upatentable over inventor Shi's previous publication, in light of other publications discussed further below.

Applicants attended an Examiner Interview with the Examiner on July 27, 2006 to discuss the basis and rationale for the rejection, and appreciate the Examiner's time and guidance therein. In this response, the Applicants respectfully (1) confirm the provisional claim election of Applicants' prior counsel, (2) amend claim 18, and (3) traverse the rejections under 35 U.S.C. § 103(a) with regard to the cited references. Applicants respectfully request reconsideration of the pending claims in view of the following remarks.

II. The Rejection Under 35 U.S.C. § 112 Should Be Withdrawn.

Pursuant to the Examiner's rejection under 35 U.S.C. § 112, Applicants have amended claim 18 to eliminate the inclusion of oximes and phosphates that have proven toxic as nerve

agents. Further, the recited structures are amply supported by the specification, including discussion at pages 32-36. Therefore, Applicants respectfully request reconsideration and withdrawl of the rejection under 35 U.S.C. § 112.

III. Overview of the Cited References.

The Examiner has rejected claims 18-24, and 27 under 35 U.S.C. 103(a) as being upatentable over inventor Shi's previous publication, Shi, *Differential Effects of Low and High Concentrations of 4-aminopyridine on Axonal Conduction in Normal and Injured Spinal Cord,* NEUROSCIENCE (Elsevier, 1997) (the "Shi Reference"); as well as a publication by Greensmith et. al., *Induction of Transmitter Release at the Neuromuscular Junction Prevents Motoneuron Death after Axotomy in Neonatal Rats*, NEUROSCIENCE (Elsevier, 1996) (the "Greensmith Reference"); or the references by "Blight, Seil, Hays, Hansebout etc. recited in the specification" of the present application on page 3 (collectively, the "Specification References"), in view of the following texts and articles: BUNDGAARD, DESIGN OF PRODRUGS 31-33, (Elsevier, 1985) (the "Bungaard Reference"); Collin R. Gardner, *Targeting the Central Nervous System: New Drug Delivery Technologies for Psychotropic Agents*, PSYCHOPHARMACOLOGY BULLETIN, Vol. 21, No. 3, 1985 (the "Gardner Reference"); and Emil Pop, *Application of a Brain-Targeting Chemical Delivery System to 9-Amino-1,2,3,4-Tetrahydroacridine*, PHARMACEUTICAL RESEARCH, Vol. 7, No. 6, 1990 (the "Pop Reference"). Collectively, the references previously cited are referred to as "the Cited References." For convenience, and as an introduction to the discussion of the rejections that follow, Applicants summarize the relevant portions of the Cited References in turn below.

A. The Shi Reference

The Shi Reference notes that 4-aminopyridine (4-AP) has been shown to effect recovery of action potential conduction in myelinated axons when applied to pathological conditions, but indicates that "the mechanism and significance of this phenomenon are not completely understood." Abstract (emphasis added). Further, the Shi Reference goes on to discuss the effects of a range of 4-aminopyridine concentrations on conductions in an experimental model of chronic spinal cord injury in guinea pigs, noting threshold levels, peak response levels, and conduction suppression levels of 4-AP when used on healthy white matter versus when used on injured white matter post injury. Further, the Shi Reference notes that the concentration and effects of 4-AP are substantially different between the central nervous system and the peripheral nervous system. *Id.* The Shi Reference does not disclose any use of compounds other than 4-AP.

B. The Greensmith Reference

The Greensmith Reference addresses the use of 4-AP on neonatal rats by injecting 4-AP into the calf muscles of the rats for three days following birth. Abstract. Specifically, the Greensmith Reference discloses treatment of neonatal rats with 4-AP injections into the calf muscles for three days, crushing the sciatic nerve, and analyzing the survival of soleus motoneuron. *Id.* Using the results of the experimentation above, the Greensmith Reference suggested that enhancing transmitter release from nerve endings in the peripheral nervous system pre-injury induces the motoneuron to become more resistant to a later nerve injury. *Id.* However, no experimentation of 4-AP effects on central nervous system injury or use of 4-AP post-injury is included in the Greensmith Reference. Further, no discussion of compounds other than 4-AP is found in the Greenmith Reference, nor is there any suggestion to modify 4-AP.

C. The Specification References

As the examiner noted in the Office Action, references from Blight, Seil, Hays, Hansebout, and others were discussed in the Background section of the present application. Each of these references was discussed individually on page 3 of the specification, ultimately noting that when 4-AP is applied to individuals with chronic spinal cord injuries or paralyzed individuals, only "about 30% of the treated population" made any meaningful recovery. Further, as noted in the specification, the references cited indicate that the systemic concentrations of 4-AP required for treatment often result in substantial and unwanted side-effects.

D. The Bungaard Reference

The Bungaard Reference is a text devoted to an editorialized summary of articles detailing possible prodrug designs for various drugs. Specifically, pages 27-33, included with the Office Action, discuss "Prodrugs for Amines." The author introduces this section by noting that "N-Acylation of amines to give amide prodrugs has been used only to a limited extent due to the relative stability of amides in vivo. However, certain activated amides are sufficiently labile and, also certain amides formed with amino acids may be susceptible to enzymatic cleavage in vivo." Pages 27-28 (emphasis added). The Bungaard Reference goes on to discuss the "new concept of obtaining site-specific and sustained release of amine drugs to the brain, involving n-acylation . . . ." Page 31. The Bungaard Reference further discusses that "several amine drugs are not sufficiently lipophilic to be able to pass the blood-brain barrier," but that experimentation by Bodor et al. shows some success in some compounds by linking the drugs to a lipohilic dihydropyridine carrier through an amide linkage allows the drug to be delivered throughout the body, including the brain. *Id.* (emphasis added). The Bungaard Reference discusses that the concept has been applied successfully only in phenethylamine, dopamine, and testosterone. Page

32. Finally, the Bungaard Reference admits that "[v]arious carbamate derivatives have been assessed as prodrugs for normeperidine, amphetamine, ephedrine, and phenethylamine, but with limited success." *Id.* (emphasis added).

However, the Bungaard Reference does not discuss the n-acylation of 4-AP, nor does it disclose the chemical structure of any of the structures currently claimed in the present application, or their likelihood of success. At best, the Bungaard Reference teaches that N-acylation of some drugs that otherwise will not pass the blood-brain barrier might allow such a prodrug to pass through the blood-brain barrier, but that past examples have been met "with limited success." *Id.*

E. The Gardner Reference

The Gardner Reference discusses various approaches to attempt drug delivery to the central nervous system, noting that most hydrophilic compounds do not cross lipophilic barriers (such as the two lipophilic cell membranes comprising the blood-brain barrier) through passive diffusion. Page 657. Further, the Gardner Reference notes that the endothelial cells and glial cells surrounding the capillary membranes contain numerous enzymes that may degrade chemicals such as drugs or prodrugs that are capable of crossing the blood-brain barrier, thereby introducing uncertainty of success for any particular structure until tested. *Id.*

The Gardner Reference discusses several varied approaches that might be attempted to try to allow a hydrophilic drug to reach the central nervous system, including: use of liposomes and other small dimension particles as "Trojan horses" to carry the drugs across the blood-brain barrier, using pumps with catheters for direct delivery to the ventricles of the brain, or by varying the chemical structure of the drug to create a prodrug or metabolic inhibitor. Pages 658-659. Potential chemical approaches for modifying drugs are further discussed based upon general

classes of drugs: (1) drugs that are not biologically available due to metabolism of the drug or incomplete transport across membranes; (2) drugs that require high doses because they penetrate poorly across the blood-brain barrier; and (3) drugs that require high doses because they are the target of several receptors, enzymes, or uptake sites in many tissues throughout the body. Pages 658-660.

The Gardner Reference cites the research by Bodor et al. (discussed above in the Bungaard reference) discussing one strategy for improving compounds that lack effectiveness or require high doses due to poor penetration across the blood-brain barriers. Specifically, the Gardner Reference discusses Bodor's general approach to attach a lipophilic functional group to a hydrophilic drug. Page 660. The Gardner Reference notes that effectiveness of such a prodrug depends not only upon the ability to cross the blood-brain barrier, but also upon conversion from the pro-drug form to the drug form once the complex reaches the central nervous system. *Id.* Otherwise, the prodrug is allowed to pass back and forth between the central nervous system and the peripheral nervous system unimpeded. *Id.* The Gardner Reference goes on to say that this approach has provided "some interesting data," citing Bodor & Simpkins (1983), but notes that "there still remain a number of important questions concerning the stability of these agents, their oral absorption, the rate of cleavage of the drug-carrier bond, and the potential toxicity of the carrier system." *Id.*

The Gardner Reference does not disclose the use of 4-AP, nor does it indicate which approach to modifying would lead to successful drug delivery. Further, the Gardner Reference does not teach that any of the strategies or approaches discussed generally will be effective for any specific drug or chemical other than those specifically discussed. Rather, the Gardner Reference admits that "[w]hile serendipity will always play an important role, information

concerning means of modifying absorption, distribution, and metabolism of drugs should be used to design rational approaches to optimization of drug effectiveness." Page 661 (emphasis added). Therefore, the Gardner Reference admits that its disclosure merely provides rational approaches to attempt (or thoughts on experiments to try) when optimizing drug delivery, but admits that actually finding success in such approaches requires some "serendipity."

F. The Pop Reference

The Pop Reference discusses the preparation and testing of several chemical delivery systems synthesized for the cholinesterase inhibitor 9-amino1,2,3,4-tetrahydroacridine ("THA") for use as a treatment of senile dementia caused by Alzheimer's. Page 658. Specifically, the chemical delivery systems tested were designed in an effort to decrease liver toxicity of THA by adding "various molecular carriers, such as 1-alkyl-1,4-dihydronicotinates, 1-alkyl-1,4-dihydronicotinic dihydronicotinamides, or other 1-alkyl-1,4-dihydronicotinic acid derivatives" in an effort to enhance lipophilicity of the conjugates and sequestering of the dihydropyridine derivative in the central nervous system once the complex is oxidized. *Id.* While the Pop Reference noted that this general approach to developing a chemical delivery system had proven successful in drugs such as dopamine, γ-aminobutyric and tryptamine, sex steroids, and others, "several *potential* brain-targeting derivatives of THA were synthesized . . . ." Page 661 (emphasis added).

The Pop Reference further teaches that a basic tenet of developing a chemical delivery system to the central nervous system is to substantially reduce the pharmacological/toxicological potential by ensuring that the prodrug (e.g. a depoted pyridinium salt) is inert until it is oxidized. Pages 663-664. In the Pop Reference, the tested prodrug (formulation 3a) was shown to have an in vitro pharmacological activity almost 100 times less than the drug form, THA. *Id.* Therefore,

the Pop Reference teaches that a prodrug form of a drug should be inert prior to conversion in vivo into the drug form. *See, Id.*

The Pop Reference does not discuss the use of 4-AP, nor does it teach that N-(4-pyridyl) methyl carbamate; N-(4-pyridyl) ethyl carbamate; or n-(4-pyridyl) t-butyl carbamate would be an effective treatment for spinal cord injuries. Further, the Pop Reference teaches that in order for the abovementioned compositions to be considered prodrug under the general chemical delivery systems theories discussed in the Bungaard Reference or the Gardner Reference, those compositions should be inert under in vitro testing, as the prodrug must be converted to a drug prior to becoming active.

IV. The Rejection of Claims Under 35 U.S.C. § 103(a) Should Be Withdrawn.

The Examiner has initially rejected Claims 18-24, and 27 under 35 U.S.C. §103, indicating that the Cited References, when considered together, disclose that N-acylation of 4-aminopyridine would obviously produce a drug that would restore action potential conduction through spinal cord lesions at a lower systemic concentration than 4-aminopyridine. Specifically, the Examiner indicated that N-acylation as taught by the Bungaard Reference is expected to produce a lipophilic prodrug that more readily passes the blood-brain barrier as taught by the Gardner Reference. The Examiner goes on to note that since the Shi Reference and the Specification References disclose that 4-aminopyridine has action potential function, the Examiner reasoned that N-acylation of this drug would produce a more effective prodrug.

Applicants posit that the Examiner's rejection under 35 U.S.C. 103 should be reconsidered and withdrawn, as the Cited References: (1) do not disclose each element of claims in the present application, (2) disclose no motivation for utilizing N-(4-pyridyl) methyl carbamate; N-(4-pyridyl) ethyl carbamate; or n-(4-pyridyl) t-butyl carbamate for treatment of a

spinal cord injury, and (3) disclose no reasonable expectation of success when the Cited References are combined. As further discussed below, Applicants respectfully request the rejections be removed, and the claims of the present application be allowed.

A. The Examiner Has Failed to Make a Prima Facie Case of Obviousness

A prima facie case of obviousness requires: (1) some suggestion or motivation to modify the references or combine the reference teachings, (2) a reasonable likelihood of success in modifying the cited references, and (3) the cited references must contain all of the limitations of the claims. MPEP §2143; *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998).

When applying 35 U.S.C. § 103(a) to chemical cases, the United States Court of Appeals for the Federal Circuit (the "CAFC") has further established that a disclosed generic formula that encompasses a claimed compound does not by itself render the claimed compound obvious. *In re Baird*, 16 F.3d 380, 382 (Fed. Cir. 1994). Rather, the court reasoned that a prior art reference that encompasses a "potentially infinite genus" may on its face cover a claimed compound, but not fairly render the claimed compound obvious because the claimed compound is not sufficiently enabled. *See Id.* This particular rule has been applied by the Board of Patent Appeals and Interferences in its decision *Ex Parte Anwar A. Hussain* to find that disclosure of a group of testosterone prodrugs in prior art did not render obvious the specific subgenus of testosterone analogs claimed by the applicant. Appeal No. 1999-1472. Thus, a general disclosure of a particular class of compounds, drugs, or prodrugs does not automatically render a claimed subgenus or species of that class obvious.

Further, in determining whether references render a claimed invention obvious, the CAFC clearly stated that it is improper to reject a claim as obvious based upon prior art that simply indicates that a claimed invention is "obvious to try" in light of a particular problem to be

solved. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). In particular, the court indicated that citation of general approaches "that seemed to be a promising field of experimentation" does not properly establish obviousness, particularly "where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Id.* As such, general discussions in the prior art which indicate that altering functional groups on general classes of compounds might cause a desired property in a compound do not render obvious a particular claimed compound. Instead, such citations simply indicate that altering functional groups in such a fashion might be "obvious to try" when a particular property is desired. However, this is not the standard for obviousness under 35 U.S.C. §103, and such an argumentation is improper. *Id.*

B. The Cited References Do Not Disclose All Limitations of the Cited Claims

As discussed in the Overview of the Cited References above, even when combined, the Cited References do not disclose each and every one of the limitations of the claims. Foe example, as noted above, none of the Cited References disclose the "pharmaceutical composition, or pharmaceutically acceptable salt or solvate thereof, selected from the group consisting of: *N*-(4-Pyridyl) *t*-Butyl Carbamate; *N*-(4-Pyridyl) Ethyl Carbamate; *N*-(4-Pyridyl) Methyl Carbamate; or *N*-(4-Pyridyl) Isopropyl Carbamate" limitation of independent claim 18. Further, for example, none of the Cited References disclose the "pharmaceutical compound comprising N-4-Pyridyl Carbamate" limitation of independent claim 29, nor is there any disclosure of a class of compounds that would encompass any of these compositions or class of compositions being used for restoration of action potential in injured spinal tissue.

Rather, the Examiner's rejection is based upon the supposition that prior knowledge of action potential restoration by 4-aminopyridine in both central and peripheral nervous system

tissue, coupled with general teachings of general "approaches" to modification of general classes of drugs to target the central nervous system renders the Applicant's claims obvious—even when no specific teaching of modifying 4-aminopyridine is cited. Thus, Applicants note that the Cited References do not disclose each and every limitation of the independent claims herein, and the Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 18.

C. No Motivation to Combine—Specification Suggests not a Prodrug

As discussed above, a prima facie case of obviousness requires some suggestion or motivation to modify the references or combine the reference teachings. The Examiner indicates that the Cited References teach a motivation in the art to create a prodrug to target the central nervous system. However, as discussed in the Examiner Interview, and as further defined in the Cited References, to be considered prodrug under the general chemical delivery systems theories discussed in the Bungaard Reference, the Gardner Reference, or the Pop Reference, a composition should be inert until converted from the prodrug form to the drug form in vivo. Thus, under in vitro testing, a prodrug should not show activity because a prodrug by definition is not active until converted to a drug form in vivo. However, Applicants' disclosure clearly indicates that the claimed compounds are effective when directly applied to spinal cord tissue, as discussed in pp. 24-27 of the specification. Such effectiveness indicates that the claimed compounds themselves exhibit biological activity, rather than being inactive until converted to 4-aminopyridine. Thus, the specification of the present application suggests that the compounds used in the claimed methods do not behave as prodrugs, but as drugs themselves.

To the contrary, the Gardner Reference teaches away from designing a prodrug that is biologically active, as the Gardner Reference teaches that effectiveness of a prodrug depends not

only upon the ability to cross the blood-brain barrier, but also upon conversion from the pro-drug form to the drug form. Gardner Reference, p. 660. The Gardner Reference further teaches that once a prodrug passes the blood brain barrier, that the lipohilic group should no longer be active to prevent the compound from passing back out of the central nervous system. *Id.* However, since the compounds in the claimed methods show biological activity when directly applied to spinal tissue in vitro, there is no apparent conversion from a prodrug to a drug or from lipophilic to hydrophilic forms as taught by the Gardner Reference. As such, there would be no motivation to combine a reference to prodrug design in an instance where testing disclosed in the specification indicates that the compounds used in the claimed method are not prodrugs.

The Examiner has cited multiple references teaching the modification of various drugs (not including 4-aminopyridine) to create a prodrug. However, Applicants' specification bears out testing indicating that the claimed compounds have biological activity without conversion of those compounds into another chemical. Thus, Applicants respectfully contend that there is no motivation to combine teachings of general approaches to prodrug design with the Shi Reference, Specification References, or Greensmith Reference to create a compound which shows biological activity. Rather, the Gardner, Bungaard, and Pop references teach that a modification of a drug to target the central nervous system should result in a prodrug that has no biological activity until the compounds are converted to the active drug from which it was formed. As pointed out above, the specification of the present application bears out that the claimed compounds have biological activity without conversion, as activity is shown when an aqueous solution of the compounds is administered to injured spinal tissue in vivo. As such, Applicants request reconsideration and withdrawal of the rejections to claim 18 under 35 U.S.C. § 103.

D. The Examiner Has not Shown a Reasonable Likelihood of Success

A prima facie case of obviousness requires a showing of a reasonable likelihood of success in modifying the cited references. However, the Gardner Reference specifically indicates that the teachings therein do not show a reasonable likelihood of success. Rather, the Gardner Reference teaches that when the general approaches and combinations recommended therein require that "serendipity will always play an important role." Gardner Reference, p. 661. Further, as discussed above, the Bungaard Reference summarized the current research by stating that "certain activated amides are sufficiently labile and, also certain amides formed with amino acids may be susceptible to enzymatic cleavage in vivo," but did not indicate with certainty which amides will be sufficiently labile, or which might be susceptible to enzymatic cleavage in vivo. Bungaard Referenc, pp. 27-28 (emphasis added). Further, of the research cited for specific compounds, it was noted that Since the Cited References themselves teach that the general approaches and designs set forth therein still require luck even when specifically followed, such a reference, or combination of such references, cannot be said to provide a reasonable likelihood of success.

The Pop Reference teaches the modification of 9-amino1,2,3,4-tetrahydroacridine by testing nine molecular carriers in an attempt to create a prodrug that is more effective in reaching the central nervous system. Thus, the Pop Reference, which teaches particular modifications to a base compound unrelated to 4-aminopyridine (9-amino1,2,3,4-tetrahydroacridine), further shows that experimentation and changing of multiple variables is needed to produce a viable prodrug even when the mechanism of the underlying compound is well understood.

Further, it should be noted that modification of 4-aminopyridine is not taught in any of the Cited References. The Bungaard Reference notes that even the modifications for the specific

compounds discussed have been met "with limited success," indicating that the application of the general concepts therein to other chemicals would not likely be successful. Bungaard Reference, p. 32. Therefore, even if the Cited References specifically addressed the modification of 4-aminopyridine (which they do not), the best result that could be expected would be "limited success" or success by serendipity. Applicants respectfully contend that such an expectation, as taught by the Cited References, does not meet the threshold for a prima facie case of obviousness.

Rather, Applicants contend that when the Cited References are considered as a whole, they disclose, at best, a general approach that seems to be promising in a field of experimentation. However, in *In re O'Farrell*, the CAFC established that disclosures of a general approach that seems to be promising in a field of experimentation does not establish a prima facie case of obviousness, but only establish that it would be "obvious to try" a number of combinations until a successful result is obtained. In this instance, the Gardner, Bungaard, and Pop References do not even specifically address the class of compounds claimed. Rather, the citations cover "Prodrugs for Amines" (Bungaard Reference, p. 27), normeperidine, amphetamine, ephedrine, phenethylamine, (*Id.*) and dopamine, testosterone, phenethylamine, tryptamine, and 9-amino 1,2,2,4-tetrahydroacridine, (Pop Reference, p. 661) and note that many of the teachings are met with "limited success." Bungaard Reference, p. 27.

Finally, the BPAI, in a previous hearing, has overturned an examiner's finding of obviousness with far stronger prior art than those cited in this case. Specifically, in *Ex Parte Anwar A. Hussain*, the BPAI found that a broad disclosure of charged testosterone prodrugs did not render obvious a subgenus of testosterone analogs claimed by Hussain. The BPAI explicitly rejected the argument set forth by the examiner "that the disclosure of a chemical genus renders

obvious any species that happens to fall within it." Appeal No. 1999-1472, p. 6. In this instance, the Examiner's cited references deal with teachings regarding an even more broad chemical genus than those identified—"Prodrugs for Amines" in the Bungaard Reference, approaches to attempt drug delivery to the central nervous system in the Gardner Reference, and an unrelated cholinesterase inhibitor in the Pop Reference. Therefore, since the references cited by the Examiner are even less related to the claims than those that were rejected by the BPAI, Applicants respectfully request that the rejection be withdrawn.

Therefore, there is no likelihood of success because (1) the Bungaard and Gardner References specifically teach that limited success is be expected unless serendipity plays a role, (2) the Pop Reference teaches that several molecular carriers must be tested to find a combination that produces an effective prodrug to target the central nervous system, and (3) the Bungaard, Gardner, and Pop References do not reference 4-aminopyridine as a potential substrate for producing a prodrug, and even the listed compounds cited as examples enjoy only "limited success" in the Bungaard Reference. For these reasons, Applicants respectfully submit that the rejection under 35 U.S.C. §103 should be withdrawn.

V. Claims 19-22, 24-26, and 29 Should Be Allowed

Claims 19-22, 24-26, and 29 depend from allowable claim 18, and import all the limitations therein. As such, Applicants respectfully request allowance of those claims.

VI. Conclusion

For all the foregoing reasons, it is respectfully submitted that the Applicants have made a patentable contribution to the art and that this response places the above identified application in condition for allowance, or in the alternative this response places the application in a better form for appeal. Favorable reconsideration and allowance of this application is respectfully requested.

Should the Examiner continue to find any of the Claims objectionable for any reason, the Examiner is respectfully requested to contact the undersigned for a telephone interview before taking further action. Applicants hereby respectfully petition for a three month extension of time to respond, and authorize payment of the fee to be charged to deposit account 09-0007. In the event the Applicants have inadvertently overlooked the need for an extension of time or payment of an additional fee, the Applicants conditionally petition therefor, and authorize any fee deficiency to be charged to deposit account 09-0007.

Respectfully submitted,

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9/21/06

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